**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF TEXAS**
**DALLAS DIVISION**

| | | |
|---|---|---|
| **UNITED STATES OF AMERICA** | | |
| **v.** | | **No. 3:15-cr-00496-L** |
| **USPLABS, LLC** | **(1)** | |
| **JACOBO GEISSLER** | **(2)** | |
| **JONATHAN DOYLE** | **(3)** | |
| **MATTHEW HEBERT** | **(4)** | |
| **S.K. LABORATORIES, INC.** | **(5)** | |
| **SITESH PATEL** | **(6)** | |

**DEFENDANTS USPLABS, LLC, JONATHAN DOYLE, JACOBO GEISSLER, MATTHEW HEBERT, S.K. LABORATORIES, INC. SITESH PATEL AND KENNETH MILES'S MOTION AND BRIEF TO DISMISS COUNTS NINE AND TEN FOR UNCONSTITUTIONAL VAGUENESS**

Defendants USPlabs, LLC ("USPlabs"), Jonathan Doyle, Jacobo Geissler, and Matthew Hebert (collectively, the "Owner Defendants"), Kenneth Miles, S.K. Laboratories ("S.K. Labs"), and Sitesh Patel, by and through undersigned counsel, respectfully move this Court to dismiss Counts Nine and Ten of the First Superseding Indictment [Dkt. No. 95, filed Jan. 5, 2016] (the "Indictment"). Counts Nine and Ten – strict-liability misdemeanor charges for misbranding and adulteration, respectively – must be dismissed because they are based on statutes that are void for vagueness, in violation of the Fifth Amendment's Due Process Clause. Defendants would respectfully show the Court as follows.

**TABLE OF CONTENTS**

# TABLE OF AUTHORITIES

**Page(s)**

**Cases**



**Statutes**

**Other Authorities**

## I. SUMMARY OF THE ARGUMENT

USPlabs is a dietary supplement own-label distributor; SK Labs is a contract manufacturer that manufactured USPlabs' supplements and consulted on supplement formulation. In November 2015, the Government indicted USPlabs, its three principals (Geissler, Doyle, and Hebert), one of its consultants (Willson), and its compliance officer (Miles), and SK Labs and one of its employees (Patel) on a number of counts relating to Defendants' importation of dietary ingredients and marketing and sale of dietary supplements containing those ingredients. Counts Nine and Ten of the Indictment allege strict-liability misdemeanor charges for misbranding and adulteration, respectively, relating to two supplements that USPlabs marketed for brief periods of time: OxyELITE Pro Advanced Formula ("Advanced Formula") and OxyELITE Pro New Formula ("New Formula"). Both counts should be dismissed as unconstitutionally vague.

21 U.S.C. § 333(a)(1) – the provision under which both Counts Nine and Ten are charged – is unconstitutionally vague for two reasons. First, it lacks a scienter requirement. As such, it would permit a defendant to be convicted without any *mens rea* as to the underlying facts of adulteration or misbranding, even if someone other than the defendant took the relevant actions. Second, the purported substitute for scienter – the requirement that a defendant have a position of "responsibility" within a company at which misbranding or adulteration occurs – has not been given any discernable standards by Congress or the courts.

Beyond these fatal defects, the underlying substantive statutes – 21 U.S.C. § 343(a)(1) for misbranding, and 21 U.S.C. § 342(f)(1)(A)(i) for adulteration – also suffer from their own vagueness problems when applied to the facts of this case. When these problems are combined with a criminal enforcement statute that lacks an intent requirement, charges based on these

statutes cannot withstand Constitutional scrutiny. Counts Nine and Ten must therefore be dismissed.

## II. INTRODUCTION AND BACKGROUND

Counts Nine and Ten relate to two of USPlabs' products: Count Nine, the misbranding count, relates to OxyELITE Pro Advanced Formula ("Advanced Formula"), and Count Ten, the adulteration count, relates to OxyELITE Pro New Formula ("New Formula"). New Formula contained an ingredient called Aegeline, which is derived from the Bael plant, which has been consumed as food for thousands of years; Advanced Formula contained both Aegeline and extract of *cynanchum auriculatum* ("Cynanchum"), a plant found throughout Asia that has also been consumed as food for many years. USPlabs began marketing New Formula in November 2012, followed by Advanced Formula in August 2013.[1] Dkt. #95 ¶¶ 29, 32.

The Indictment makes two different allegations regarding these two dietary supplements: In Count Nine, the Government alleges that Advanced Formula was misbranded because its label declared Cynanchum as "cynanchum auriculatum (root) extract." According to the Government, this labeling "was false and misleading" within the meaning of 21 U.S.C. §343(a)(1) because the Cynanchum in Advanced Formula was in powder form, not an extract (even though most extracts are in powder form).[2] *Id*. ¶¶ 63, 68.

In Count Ten, the Government conclusory alleges that New Formula "presented a significant or unreasonable risk of illness or injury under the conditions of use recommended or

[1] USPlabs voluntarily took Advanced Formula off the market after only 65 days as part of USPlabs' efforts to cooperate with the Government's investigation into a purported liver injury cluster in Hawaii. USPlabs and the other Defendants believed at all times (and still believe to this day) that Advanced Formula was safe and are aware of no evidence showing otherwise.

[2] As explained in other motions, Count 9 is also subject to dismissal because the only document referenced in the Indictment supporting this allegation established that the Cynanchum USPlabs used in Advanced Formula was, in fact, an extract.

suggested in labeling," in violation of the standards set forth in 21 U.S.C. § 342(f)(1)(A)(i). *Id.* The Indictment does not specify what in particular made New Formula adulterated, but it appears from elsewhere in the Indictment that this relates to USPlabs' use of Aegeline in New Formula. *Id*. ¶¶ 33, 35. However, the Indictment does not point to any scientific study supporting the conclusion that either aegeline or any other dietary ingredient in New Formula presents a risk of consumer harm, any scientific evidence establishing any causative link between Aegeline (or any other New Formula ingredient) and injury to any New Formula consumer, or any scientifically based conclusion by FDA that Aegeline or any other New Formula ingredient posed any risk of harm.[3]

## III. ARGUMENTS AND AUTHORITIES

Counts 9 and 10 should be dismissed because they are unconstitutionally vague. First, Section 331(a)(1), both by its express terms as interpreted by the Supreme Court, lacks a clear intent requirement, and is therefore unconstitutionally vague for that reason alone. Second, the two statutory provisions underlying Counts 9 and 10 - §§ 343(a)(1) and 342(f)(1)(A)(i), respectively – are also unconstitutionally vague as applied here, as they lack any discernible standards that place Defendants on notice as what conduct these provisions proscribe. Because Counts 9 and 10 combine the Constitutionally deficient strict-liability standard of § 333(a)(1) with each of these unconstitutionally vague provisions, these Counts must be dismissed.

### A. APPLICABLE LAW

To determine whether a statute is unconstitutionally vague, the Fifth Circuit employs a multi-factor test that evaluates the following factors: (1) whether the statute at issue in an

[3] To the contrary, Defendants will establish through the testimony of multiple experts at trial that Aegeline posed no harm to consumers of New Formula (or any other USPlabs supplement).

economic regulation, as a party may seek clarification of an economic regulation from the relevant agency if necessary; (2) the amount of notice that a party has that its conduct was proscribed; (3) whether the regulation at issue include a scienter requirement or is a strict-liability offense; and (4) whether the violation of the regulation exposes the violator to civil penalties, or to criminal ones. *See United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 122-23 (5th Cir. 1991); *Roark & Hardee LP v. City of Austin*, 522 F.3d 533, 551-52 (5th Cir. 2008); *see also Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982).

An unconstitutionally vague provision is not rendered constitutional "merely because there is some conduct that clearly falls within the provision's grasp." *Johnson*, 135 S. Ct. at 2561. In *Johnson*, for example, the Supreme Court passed on the constitutionality of the residual clause to the Armed Career Criminal Act, which applies to persons with three or more convictions of a "violent felony," which the Act defined to include "any crime punishable by imprisonment for a term exceeding one year . . . that [among other possibilities] or otherwise involves conduct that presents a serious potential risk of physical injury to another." *Johnson*, 135 S. Ct. at 2555-56. The Court explained that its own struggle to define this residual clause and the category of conduct that it applied to rendered it unconstitutionally vague. *Id*. at 2557-60 ("Nine years' experience trying to derive meaning from the residual clause convinces us that we have embarked upon a failed enterprise. Each of the uncertainties in the residual clause may be tolerable in isolation, but their sum makes a task for us which at best could be only guesswork." (internal quotation marks omitted)).

The recognition in the *Clinical Leasing* factors that a strict-liability criminal statute raises Constitutional concerns reflects a long tradition in the criminal law of requiring *mens rea* before

declaring an individual's conduct to be criminal. As the Supreme Court put it more than half a century ago,

> [t]he contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion. It is as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil.

*Morissette v. United States*, 342 U.S. 246, 250-51 (1952). Accordingly, "[w]hile strict liability crimes are not unknown to the criminal law and do not invariably offend constitutional requirements, the limited circumstances in which Congress has created and [the Supreme Court] has recognized such offenses, attest to their generally disfavored status." *United States v. U.S. Gypsum Co.*, 438 U.S. 422, 437-38 (1978). As the Fifth Circuit has recognized, "[s]trict liability exacerbates vagueness. . . ." *Okpalobi v. Foster*, 190 F.3d 337, 360 (5th Cir. 1999), *vacated on other grounds*, 244 F.3d 405 (5th Cir. 2001); *see also Vill. of Hoffman Estates*, 455 U.S. at 499 (noting that "a scienter requirement may mitigate a law's vagueness, especially with respect to the adequacy of the notice to the complainant that his conduct is proscribed.").

### B. COUNTS NINE AND TEN SHOULD BE DISMISSED BECAUSE MISDEMEANOR LIABILITY UNDER THE FDCA IS A STRICT LIABILITY OFFENSE.

21 U.S.C § 333(a)(1) – the statute under which Counts Nine and Ten are brought – is essentially a strict-liability offense, and ***does not*** require the Government to prove that a defendant acted with an intent to defraud or mislead. Instead, the Supreme Court has interpreted § 333(a)(1) to allow a defendant to be convicted of an adulteration or misbranding misdemeanor if he "had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, [but] failed to do

so." *United States v. Park*, 421 U.S. 658, 673-74 (1975) (quotation marks and citations omitted); *see also United States v. Dotterweich*, 320 U.S. 277, 285 (1943).

Thus, notwithstanding the *Park* doctrine, Counts Nine and Ten must be dismissed because § 333(a)(1)'s lack of a scienter requirement renders these Counts unconstitutionally vague.

**1. Counts Nine and Ten Are Unconstitutionally Vague Because 21 U.S.C § 333(a)(1) Lacks a Clear Scienter Requirement.**

While Counts Nine and Ten allege certain Defendants violated different underlying substantive statutes, they are both enforced via 21 U.S.C § 333(a)(1). That statute makes it a misdemeanor to introduce into interstate commerce "any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded," in violation of 21 U.S.C § 331(a). Unlike most other criminal statutes, however, 21 U.S.C § 333(a)(1) does not include a scienter requirement, and is essentially a strict liability offense. *United States v. Park*, 421 U.S. 658, 673-74 (1975) ("The [Food, Drug & Cosmetic] Act does not, as we observed in *Dotterweich*, make criminal liability turn on 'awareness of some wrongdoing' or 'conscious fraud.'"); *see also United States v. Dotterweich*, 320 U.S. 277, 285 (1943). Equally important, the class of persons susceptible to prosecution under Section 333(a)(1) is not subject to any clear limit. *See Dotterweich*, 320 U.S. at 285.

In both *Park* and *Dotterweich*, the Supreme Court affirmed the conviction of corporate executives under Section 331(a) for the sale of misbranded or adulterated food by the corporations they were in charge of; no evidence was presented indicating that the executives had any individual role in any wrongdoing. *See Park*, 421 U.S. at 672-74 (affirming conviction of CEO of corporation for sale of adulterated food based on finding that food was stored in

warehouses with rat infestations); *Dotterweich*, 320 U.S. at 284-85 (affirming conviction of president and general manager of pharmaceutical corporation of two counts of misbranding and one count of adulteration). The defendant executives in both cases were subjected to fines, but neither argued that their prosecution under Section 333(a)(1) was unconstitutionally vague.[4]

Section 333(a)(1)'s lack of a scienter element, as determined in *Park* and *Dotterweich*, renders it unconstitutionally vague – an issue neither the *Park* nor the *Dotterweich* courts addressed.[5] It is well settled that, "as a matter of due process, a criminal statute that fails to give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden by the statute, or is so indefinite that it encourages arbitrary and erratic arrests and convictions, is void for vagueness." *Colautti v. Franklin*, 439 U.S. 379, 390 (1979); *Johnson v. United States*, 135 S.Ct. 2551, 2556-57 (2015) (holding residual clause of Armed Career Criminal Act was void for vagueness).

*Colautti*, a case decided after both *Dotterweich* and *Park*, is instructive here. In that case, the defendants sought to enjoin enforcement of a statute that required a doctor to observe a stated standard of care if (1) he determined that a fetus was viable, or (2) there was "sufficient reason to believe that the fetus may be viable." 439 U.S. at 391 (citation omitted). That standard was inherently vague because it failed to make clear "whether the statute [imported] a purely

[4] *See* Pet. for Writ of Cert., *Dotterweich*, 320 U.S. 277 (No. 5) (omitting any constitutional citations or argument); Br. for the United States, *Dotterweich*, 320 U.S. 277 (No. 5), 1943 WL 54821 (same); Br. for the Resp't, *Dotterweich*, 320 U.S. 277 (No. 5), 1943 WL 54822 (same); Pet. for Writ of Cert., *Park*, 421 U.S. 658 (No. 74-215), 1974 WL 354412; Br. for Resp't in Opp'n, *Park*, 421 U.S. 658 (No. 74-215), 1974 WL 354411 (same); Br. for Resp't, *Park*, 421 U.S. 658 (No. 74-215), 1974 WL 370189 (same); Reply Br. for the United States, *Park*, 421 U.S. 658 (No. 74-215), 1974 WL 370186 (same).

[5] *Dotterweich* and *Park* both predate the passage of the Dietary Supplement Health and Education Act ("DSHEA"), which was signed into law on October 25, 1994. It was the DSHEA that amended the FDCA to include an adulteration provision for dietary supplements. See DSHEA § 4 (codified at 21 U.S.C. § 342(f)(1)). And it was the DSHEA that brought dietary supplements within the meaning of the term "food," and thereby within the ambit of the FDCA's misbranding provision. See DSHEA § 3 (codified at 21 U.S.C. § 321(ff)). Accordingly, *Dotterweich* and *Park* did not address the unique vagueness issues that have arisen around the regulation of dietary supplements.

subjective standard or . . . a mixed subjective and objective standard." *Id.* at 391. Thus, because the law "subject[ed] the [defendant] to potential criminal liability ***without regard to fault***," the Supreme Court declared the entire statute "void on its face." *Id.* at 394-96 (emphasis added).

So too here. Section 333(a)(1) contains no language requiring any finding of fault on the part of a defendant charged thereunder. Indeed, by deliberately declining to formulate any standards resembling an intent requirement under § 333(a)(1), *Dotterweich* and *Park* created a vagueness problem that courts have yet to rectify. Indeed, the Supreme Court in *Dotterweich* recognized the vagueness inherent in the strict-liability standard that it applied to Section 333(a)(1), making it applicable to an unknown class of corporate decision-makers:

> To attempt a formula embracing the variety of conduct whereby persons may responsibly contribute in furthering a transaction forbidden by an Act of Congress, to wit, to send illicit goods across state lines, ***would be mischievous futility***. In such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted. Our system of criminal justice necessarily depends on conscience and circumspection in prosecuting officers, even when the consequences are far more drastic than they are under the provision of law before us.

*Dotterweich*, 320 U.S. at 285 (internal citation and quotation marks omitted, emphasis added); *see also id*. at 287 (Murphy, J. dissenting) (noting that the FDCA simply does not make "any reference to corporate officers" as individuals who may be held criminally liable for the actions of other employees).

*Park* likewise declined to create any standards that would clarify the scope of the doctrine, reasoning that it was "'too treacherous' [to] attempt 'to define or even to indicate by way of illustration the class of employees'" who could be convicted of FDCA misdemeanors based on their status as a "responsible" corporate officer. *Park*, 421 U.S. at 669 (quoting

*Dotterweich*, 320 U.S. at 285). Instead, it noted that a corporate officer's responsibility would "depend[] 'on the evidence produced at the trial and its submission – assuming the evidence warrants it – to the jury under appropriate guidance.'" *Id.* (quoting 320 U.S at 285).

Subsequent case law has failed to inject discernible standards into the *Park* doctrine. As one scholar put it, the "level of supervisory control an executive must have to be held criminally responsible . . . has remained unanswered in the Supreme Court and lower court opinions." Katrice Bridges Copeland, *The Crime of Being in Charge: Executive Culpability and Collateral Consequences*, 51 Am. Crim. L. Rev. 799, 815 (2014). Another pair of scholars simply stated that, under the law as it currently stands, "[t]here is effectively no standard for determining when the *Park* doctrine should apply. . . ." Greenberg & Brotman, *supra*, at 94.

This case exemplifies the lack of fair notice that *Park* and *Dotterweich* have created for potential defendants, making Section 333(a)(1) unconstitutionally vague. Three of the defendants charged with Count Nine – Miles, SK Labs, and Patel – are not executives or even control persons of USPlabs. Two are not even USPlabs' employees. Allowing the conviction of non-control person employees such as Miles and Patel goes far beyond the class of persons who could appropriately be held responsible for a corporation's misbranding without any showing that those employees knew or intended for the violation to occur. *See Park*, 421 U.S. at 672-74 (affirming conviction of CEO of corporation for sale of adulterated food based on finding that food was stored in warehouses with rat infestations); *Dotterweich*, 320 U.S. at 284-85 (affirming conviction of president and general manager of pharmaceutical corporation of two counts of misbranding and one count of adulteration).

If it would be an exercise in "mischievous futility," *Dotterweich*, 320 U.S. at 285, to even define the class of persons subject to prosecution under Section 333(a)(1), that class of persons

cannot possibly have notice that the statute could be applied to them. *See Johnson*, 135 S. Ct. at 2560-61. Indeed, leaving the decision of which class of persons could be subject to prosecution under Section 333(a)(1) to prosecutorial discretion is the epitome of the lack of fair notice that the Fifth Amendment requires. *See Johnson*, 135 S. Ct. at 2557-60. Accordingly, the lack of a scienter requirement in § 333(a)(1) renders that provision of the FDCA unconstitutionally vague, even without consideration of the other vague statutes at issue in Counts Nine and Ten. Those Counts should be dismissed for this reason alone.

### C. COUNTS NINE AND TEN SHOULD BE DISMISSED BECAUSE THEY ARE EACH BASED ON UNCONSTITUTIONALLY VAGUE STATUTES AS APPLIED HERE.

In addition to being unconstitutionally vague due to Section 333(a)(1)'s lack of an intent requirement, each of Counts Nine and Ten present additional and independent due process concerns. Count Nine is unconstitutionally vague because whether the labeling at issue is "false and misleading" turns on the meaning of a term that is nowhere defined by statute or regulation. Similarly, Count Ten's "unreasonable or significant risk of illness or injury" requirement presents an open-ended standard that is similarly incompatible with due process. Counts Nine and Ten must therefore be dismissed.

#### 1. Count Nine Must Be Dismissed Because 21 U.S.C. § 343(a)(1) Is Unconstitutionally Vague as Applied to This Case.

Count Nine charges certain Defendants with misbranding Advanced Formula because that dietary supplement listed the Cynanchum included in it as an extract when, according to the Government, the supplement contained Cynanchum in powder form. Indictment at ¶¶ 63, __. First, the two are not mutually exclusive; indeed, most extracts come in powdered form; thus, just because USPlabs used powdered Cynanchum does not mean that it did not also use Cynanchum extract. More to the point, there are no discernable standards to determine whether

an ingredient is an extract or not – neither the FDCA nor its regulations define the term "extract." Thus, the phrase "false or misleading" is unconstitutionally vague as applied to dietary supplement label claims for "extracts."

The FDCA – as amended by the DSHEA – provides definitions for almost fifty different terms, including the term "dietary supplement." *See* 21 U.S.C. § 321(ff). While the definition of "dietary supplement" uses the word "extract," it does not indicate what the latter term means. Moreover, although Title 21 of the Code of Federal Regulations contains nearly twenty-five pages of rules for the nutritional labeling of dietary supplements – including a section specifically referencing extracts – it also fails to define what an extract is. *See* 21 C.F.R. § 101.36. The only other relevant uses of the word "extract" in the Code of Federal Regulation are found in the definition of specific ingredients – *see*, *e.g.*, 21 C.F.R. § 169.175 (defining vanilla extracts) – that do not provide generally applicable guidance to dietary supplement manufacturers.

In short, dietary supplement manufacturers have no definitive way of determining if an ingredient will qualify as an extract under the law. They cannot turn to any statute or binding regulation, and are instead left guessing, with an incorrect guess subject to punishment by criminal prosecution. This risk is particularly acute in this case because, as explained in other motions, the Cynanchum that USPlabs used in Advanced Formula met the dictionary definition of "extract."[6] As such, when applied to dietary supplements allegedly misbranded for containing ingredients that the Government alleges were not "extracts," 21 U.S.C. § 343(a)(1) is so devoid

[6] As argued in Defendants' Motion To Dismiss Counts 5, 8 and 9, the Indictment fails to allege that Defendants' identification of *cynanchum auriculatum* as an "extract" on its Advanced Formula labels is false or misleading because, as the evidence cited in the Indictment demonstrates, the ingredient was in fact an aqueous "extract," according to the dictionary definition of that term. In any event, the application of the FDCA's misbranding provision is, at best, ambiguous without a more specific statutory or regulatory definition of "extract."

of discernable standards that a person of ordinary intelligence simply cannot determine if using a particular ingredient will subject him to criminal liability. This lack of standards is exacerbated by the fact that an individual may be held liable under the *Park* doctrine even if he acted in good faith, and allows prosecutors to threaten dietary supplement manufacturers with criminal liability on little more than a whim. *See Okpalobi*, 190 F.3d at 360 ("Strict liability exacerbates vagueness. . . ."); *Vill. of Hoffman Estates*, 455 U.S. at 499 (noting that "a scienter requirement may mitigate a law's vagueness, especially with respect to the adequacy of the notice to the complainant that his conduct is proscribed"). Coupled with all of the other flaws noted above, Count Nine is based on the alleged violation of an unconstitutionally vague statute (at least as applied to extracts), and therefore must be dismissed.

**2. Count Ten Must Be Dismissed Because 21 U.S.C. § 342(f)(1)(A)(i) Is Unconstitutionally Vague as Applied to This Case.**

21 U.S.C § 342(f)(1)(A)(i), which forms the substantive basis of Count Ten, provides that a dietary supplement is adulterated if it "presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling." A close analysis demonstrates that this statute is unconstitutionally vague when applied to this case, even without addressing the lack of a scienter requirement. As such, Count Ten must be dismissed.

The adulteration statute's substantive standard – namely, that a dietary supplement is adulterated if is poses a "significant or unreasonable risk of illness" – is so open-ended that it cannot possibly survive a Constitutional vagueness challenge. This standard is Constitutionally flawed because its use of the terms "significant" and "unreasonable" is irremediably vague and ambiguous. Indeed, the Supreme Court recently found a statute that used similarly vague terms – the residual clause of the Armed Career Criminal Act – unconstitutionally vague. *See Johnson*,

135 S. Ct. at 2555-56 (defining "violent felony" to include "any crime punishable by imprisonment for a term exceeding one year . . . that [among other possibilities] or otherwise involves conduct that presents a ***serious potential risk*** of physical injury to another" (emphasis added)).

First, FDA's own interpretation of what constitutes an "unreasonable" risk under Section 342(f)(1)(A)(i) is so malleable a standard that it cannot provide fair notice to potential defendants of when they risk violations of § 343(f)(1)(A)(i). FDA has never instituted an administrative procedure to declare Aegeline (or New Formula) adulterated. Indeed, it has stated, in a rulemaking that declared a dietary ingredient unrelated to this case (ephedrine alkaloids) to be adulterated, that a determination that a dietary supplement is adulterated under Section 342(f)(1)(A)(i) requires a "risk/benefit analysis to ascertain whether the risks of the product outweigh its benefits," and that only benefits that were "supported by a meaningful totality of the evidence, given the current state of scientific knowledge" should be considered as part of this analysis. 69 Fed. Reg. 6788, 6798 (2004); *see also* 21 C.F.R. § 119.1 (final rule banning ephedrine alkaloids); *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033, 1036 (10th Cir. 2006) (upholding 21 C.F.R. § 119.1).[7] In other words, under the FDA's reading of Section 342(f)(1)(A)(i), a jury tasked with determining whether Defendants violated that provision must engage in a detailed and thorough "risk/benefit analysis" that weighs the risks of a product against its benefits, an exercise normally reserved for regulatory expertise.[8] Although the question of whether the risk posed by a dietary supplement meets the vague standards of

[7] Because ephedrine alkaloids are the ***only*** ingredients that FDA has declared on the public record to be adulterated for use in dietary supplements, regulated parties like USPlabs have little to no basis to predict how FDA will treat any given dietary ingredient that comes under scrutiny.

[8] Moreover, the FDA's reading of the statute also fails to address the problem identified *supra* – *i.e.*, under what circumstances a dietary supplement could pose a risk that was "reasonable" (*i.e.*, the benefits outweigh the risks) but nonetheless "significant" enough to be "adulterated" under § 342(f)(1)(A)(i).

"unreasonableness" or "significance" may be appropriate for a regulator to resolve, those terms are simply too vague to pass Constitutional muster in a criminal context.

Moreover, documents produced by the Government in the case make clear that even the Government internally was unclear whether Aegeline is adulterated or not.[9] FDA never subjected either Aegeline or New Formula to any notice and rulemaking process to declare it adulterated. If the agency responsible for regulating the subject matter at issue was unclear, potential defendants are certainly unclear, and a criminal prosecution on that basis is void for vagueness. *See United States v. Ward*, 2001 WL 11601628, at *11-18 (E.D. Pa. Sept. 5, 2001) (dismissing indictment where OSHA was unclear and issued misleading guidance regarding issue).[10]

Second, the statute uses disjunctive phrasing to connect the words "significant" and "unreasonable," misleadingly suggesting to the jury that the "risk" in question can only be one or the other. For example, if a dietary supplement manufacturer put a product through extensive testing and determined that it did not pose an unreasonable risk – as USPlabs did with New Formula – a jury might nevertheless consider those risks "significant." Similarly, a dietary

[9] Ex. A (noting that the FDA "completed some tox testing on aegeline and higenamine," the results of which "weren't all that exciting."); Ex. B. (acknowledging that FDA has "no information at all about the health hazards associated with aegeline."); Ex. C. (noting that "the exact role of aegeline in recent cases of liver damage is still being investigated"); Ex. D (noting that "we really do not know that illness was confined exclusively to product containing aegeline" and that "[b]ecause FDA received reports of liver injury in persons who had ingested OxyElitePro prior to the addition of aegeline (albeit infrequently), we believe it's at least possible that some cases during the study period could have been due to DMAA."); Ex. E (noting that uncertainty remained as to whether aegeline or "the combination of ingredients in OEP, rather than just the aegeline [were] causing the [reaction to] the product," and stating that "it would seem appropriate to test aegeline alone and then aegeline in various combinations" in order to determine the role of the ingredient in the alleged outbreak).

[10] Moreover, the Indictment does not alleviate these concerns by providing additional detail; rather, as explained above, and in Defendants separate Motion to Dismiss Count 10, the Indictment pleads no facts in support of it. Indeed, Count Ten does not even specify the particular ingredient the Government alleges caused New Formula to be adulterated. Counsel for USPlabs has requested basic details concerning Count Ten from the Government; to date, the Government has declined to respond with any additional specificity.

supplement with enough potential harms could be considered to have "substantial" risks, even if those risks were outweighed by its benefits, resulting in an overall risk profile was not "unreasonable." Thus, the statute leaves unclear to potential defendants under what circumstances a reasonable risk can nonetheless be "significant," or when an "unreasonable" risk might be insignificant. In either situation, a dietary supplement manufacturer has no advance notice as to what risks would be either "significant" or "unreasonable" and thus as to how to avoid criminal liability under Section 342(f)(1)(A)(i) (even where they have a good-faith basis to believe that their product is safe for human consumption), and jurors are thus left to guess the answer to that same question at trial.[11]

### D. COUNTS NINE AND TEN SHOULD BE DISMISSED BECAUSE THE OPERATION OF § 333(a)(1) WITH EACH OF THE STATUTES UNDERLYING THOSE COUNTS IS UNCONSTITUTIONALLY VAGUE.

As discussed above, both § 333(a)(1) and each of §§ 343(a)(1) and 342(f)(1)(A)(i), at least as applied to this case, independently fail to provide defendants with notice as to what conduct is proscribed under those statutes. However, when the Constitutional infirmity of § 333(a)(1) is combined with the unconstitutional vagueness of § 343(a)(1) in Count Nine and § 342(f)(1)(A)(i) in Count Ten, there should be no doubt that Counts Nine and Ten should be dismissed on Constitutional vagueness grounds.

Applying *Clinical Leasing*'s multi-factor analysis confirms that Section 333(a)(1) is unconstitutionally vague. First, Section 333(a)(1) is a criminal statute, not an economic regulation. Second, Section 333(a)(1) provides no notice to potential defendants or their potential liability. With respect to Count Nine, Defendants had no notice through any statute or

[11] Except for 21 U.S.C. § 360j(m) – which establishes the humanitarian use exemption for medical devices – no other section of the FDCA uses the words "significant" and "unreasonable" disjunctively. Accordingly, this problem is unique to the regulation of dietary supplements.

binding regulation as to what the Government's view of the definition of "extract." *See supra*, Section B.1. And with respect to Count Ten, under § 342(f)(1)(A)(i) Defendants (and jurors) are left to guess where the regulatory balance lies between the benefits of the dietary ingredient in question the risks that ingredient poses to consumers when used in accordance with the product's directions for use.

Third, Section 333(a)(1), as a basis for charging violations under §§ 343(a)(1) and 342(f)(1)(A)(i), is essentially a strict-liability offense. Under *Park* and *Dotterweich*, the Government need not show that any of the defendants intended to violate the underlying statutes, or that they even had knowledge that USPlabs was in violation of the underlying statutes. Charging Defendants with misbranding under § 343(a) and with adulteration § 342(f)(1)(A)(i) as strict-liability offenses under § 333(a)(1) weighs heavily in favor of unconstitutional vagueness. *See, e.g.*, *Okpalobi v. Foster*, 190 F.3d 337, 360 (5th Cir. 1999), *vacated on other grounds*, 244 F.3d 405 (5th Cir. 2001) ("Strict liability exacerbates vagueness. . . ."); *see also Vill. of Hoffman Estates*, 455 U.S. at 499 (noting that "a scienter requirement may mitigate a law's vagueness, especially with respect to the adequacy of the notice to the complainant that his conduct is proscribed."). *See supra* Section B.1.

Finally, violating Section 333(a)(1) through violations of § 343(a)(1) and 342(f)(1)(A)(i) exposes the defendants to criminal sanctions, including a fine and up to one year imprisonment. 21 U.S.C. § 333(a)(1). Thus, each of the factors in the Fifth Circuit's multi-factor analysis counsels in favor of finding Section 333(a)(1) unconstitutionally vague. *See United States v. Clinical Leasing Serv., Inc.*, 925 F.2d 120, 122-23 (5th Cir. 1991); *Roark & Hardee LP v. City of Austin*, 522 F.3d 533, 551-52 (5th Cir. 2008); *see also Vill. of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982).

In sum, when the problems posed by §§ 343(a)(1) and 342(f)(1)(A)(i) are considered together with Section 333(a)(1)'s lack of a scienter requirement, it becomes clear that these statutes bestow upon the Government something much more than "broad discretion" to bring misdemeanor misbranding and adulteration cases. *Colautti*, 439 U.S. at 394. Instead, the Government has essentially no barriers in bringing such cases, and can therefore easily condition "potential criminal liability on confusing and ambiguous criteria." *Id.* In short, Counts Nine and Ten are not close calls, nor do they present cases where the charges in question are merely "disfavored." *U.S. Gypsum Co.*, 438 U.S. at 437-38. Rather, they are charges that demand dismissal.

## IV. CONCLUSION AND PRAYER

For the reasons stated above, Defendants respectfully request that the Court dismiss Counts Nine and Ten of the First Superseding Indictment.

Dated: May 1, 2017

Respectfully submitted:

*/s/ CHRISTOPHER NIEWOEHNER*
Christopher Niewoehner (admitted *pro hac vice*)
Illinois Bar No. 6243575
Reid Weingarten (admitted pro hac vice)
Patrick F. Linehan (admitted *pro hac vice*)
David Fragale (admitted *pro hac vice*)

STEPTOE &JOHNSON LLP
1330 Connecticut Ave. NW
Washington, DC 20036
Phone: (202) 429-3000
Fax: (202) 429-3902
rweingarten@steptoe.com

Michael John Uhl
Texas Bar No. 20371050
FITZPATRICK HAGOOD SMITH &UHL
2515 McKinney Ave.
Dallas, TX 75201
Phone: (214) 237-0900
Fax: (214) 237-0901
muhl@fhsulaw.com

**ATTORNEYS FOR DEFENDANT USPLABS, LLC**

*/s/MICHAEL P. GIBSON*
Michael P. Gibson
Texas Bar No. 07871500
BURLESON PATE &GIBSON LLP
900 Jackson Street
Suite 330
Dallas, TX 75202
Phone: (214) 871-4900
Fax: (214) 871-7543
Email: mgibson@bp-g.com

**ATTORNEY FOR DEFENDANT JACOBO GEISLER**

*/s/ RICHARD B. ROPER*
Richard B. Roper
Texas Bar No. 01723370
THOMPSON &KNIGHT LLP
1722 Routh Street
Suite 1500
Dallas, TX 75201
Phone: (214) 969-1700
Fax: (214) 969-1751

**ATTORNEY FOR DEFENDANT JONATHAN DOYLE**

*/s/ S. CASS WEILAND*
S. Cass Weiland
Texas Bar No. 21081300
SQUIRE PATTON BOGGS (US) LLP
2000 McKinney Ave.
Suite 1700
Dallas, TX 75201
Phone: (214) 758-1504
Fax: (214) 758-1550
Email: cass.weiland@squirepb.com

**ATTORNEY FOR DEFENDANT MATTHEW HEBERT**

*/S/ JOSEPH L SHEARIN*
Joseph L Shearin
Law Offices of Joe Shearin
Texas Bar No.
2515 McKinney Ave
Suite 1400
Dallas, TX 75201
214/267-1000
Fax: 214/237-0901
Email: joeshearin@shearinlaw.net

**ATTORNEY FOR DEFENDANT KENNETH MILES**

*/S/ JOSEPH M. MCMULLEN*
Joseph M. McMullen
Cal. Bar No.
Law Offices of Joseph M. McMullen
225 Broadway Suite 1460
San Diego, CA. 92101
(619)501-2000
(619) 615-2264
joe@jmm-legal.com

**ATTORNEY FOR DEFENDANT**
**S.K. LABORATORY INC.**
(admitted *pro hac vice*)

*/S/ PATRICK Q. HALL*
Patrick Q. Hall
Cal. Bar No.
Law Offices of Patrick Q. Hall
California Bar No. 97019
401 B Street, Suite 2220
San Diego, CA. 92101
(619) 268-4040
pat@pqhlaw.com

**ATTORNEY FOR DEFENDANT**
**SITESH PATEL**
(admitted *pro hac vice*)

**CERTIFICATE OF SERVICE**

On May 1, 2017, I electronically submitted the foregoing document with the clerk of the court of the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served the U.S. Probation Officer, all counsel of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2), and the probation officer assigned to the case.

/s/ *Richard B. Roper*
Richard B. Roper